

Message Text

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61

ORIGIN HEW-06

INFO OCT-01 ISO-00 AF-10 ARA-10 EA-10 EUR-12 NEA-10 RSC-01

OES-05 NSF-02 COME-00 IO-10 L-02 CIAE-00 DODE-00

INR-07 NSAE-00 PA-02 USIA-15 PRS-01 SP-02 /106 R

66616

DRAFTED BY DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

ARA/NSC-IG:RJBLOOMFIELD (INFO)

EUR/NSC-IG:JROUSE (INFO)

AF/RA:JAANDEREGG (INFO)

EA/RA:CCHAPMAN (INFO)

NEA/RA:TGRANT (INFO)

----- 005077

R 092011Z DEC 74

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES

AMEMBASSY CANBERRA

AMEMBASSY BRUSSELS

AMEMBASSY BRASILIA

AMEMBASSY TAIPEI

AMEMBASSY SAN JOSE

AMEMBASSY QUITO

AMEMBASSY SAN SALVADOR

AMEMBASSY BONN

AMEMBASSY ATHENS

AMEMBASSY NEW DELHI

AMEMBASSY JAKARTA

AMEMBASSY ROME

AMEMBASSY KINGSTON

AMEMBASSY TOKYO

AMEMBASSY KUWAIT

AMEMBASSY BEIRUT

AMEMBASSY KUALA LUMPUR

AMEMBASSY MEXICO

AMEMBASSY WELLINGTON

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AMEMBASSY ISLAMABAD

AMEMBASSY PANAMA
AMEMBASSY LIMA
AMEMBASSY PRETORIA
AMEMBASSY MADRID
AMEMBASSY STOCKHOLM
AMEMBASSY BANGKOK
AMEMBASSY LONDON
AMEMBASSY CARACAS
AMEMBASSY LUSAKA
AMCONSUL HONG KONG
TRUST TERRITORY OF PACIFIC ISLANDS LIAISON OFFICE

UNCLAS STATE 269495

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, XX

SUBJECT: RECALL OF DIAGNOSTIC PRODUCT - FIBRINDEX

1. FDA ADVISES THAT ORTHO DIAGNOSTICS INC., U.S. HIGHWAY 202
RARITAN, NEW JERSEY 08869 IS RECALLING 14 LOTS OF A DIAGNOSTIC
PRODUCT FIBRINDEX IN ORDER TO AFFIX AN ADDITIONAL WARNING STICKER
TO EACH PACKAGE BECAUSE THE INVOLVED LOTS WERE FOUND TO BE
POSITIVE FOR HEPATITIS B ASSOCIATED ANTIGEN (HBAG) UPON
RETESTING BY A THIRD GENERATION PROCEDURE KNOWN AS
"RADIOIMMUNOASSAY" (RIA). AS SUCH, THE PRODUCT IS NOT LABELED IN
ACCORDANCE WITH THE CFR TITLE 21, PART 610.40 (B) (2),
WHICH ALLOWS SUCH A PRODUCT TO BE USED, PROVIDED THAT IT IS
PROPERLY LABELED.

2. THE PRODUCT INVOLVED IS A POWDER IN A GLASS AMPULE LABELED
IN PART "XXX THROMBIN (HUMAN) FIBRINDEX XXX 50UNITS XXX WARNING:
NOT FOR HUMAN
ADMINISTRATION LOT NO. EXP.: XXX ORTHO DIAGNOSTICS INC.,
RARITAN, NEW JERSEY XXX US LIC. 156 XXX." TWELVE AMPULES ARE
PACKAGED IN A BOX SIMILARLY LABELED AS ABOVE WITH TWO INSERTS;
ONE LABELED IN PART "XXX TO OPEN PRESCORED AMPULE XXX,"
AND THE OTHER IS LABELED IN PART, XXX FIBRINDEX XXX THROMBIN
(HUMAN) XXX 50 UNITS XXX WARNING XXX PREPARATION RESULTS XXX
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BIBLIOGRAPHY XXX ORTHO DIAGNOSTICS INC., RARITAN , NEW JERSEY XXX
REVISED JANUARY , 1974 XXX 631-20-941-7 XXX MARCH 1974 XXX."

3. THE LOT NUMBERS INVOLVED ARE AS FOLLOWS: 4K-160, 4L-173,
5L-178, 6L-179, 6L-181, 6L-182, 7L-183, 7L-184, 7L-185, 8L-186,
8L-187, 9L-190, 9L-193, 10L-194.

4. FOREIGN CONSIGNEES AS FOLLOWS:

JOHNSON AND JOHNSON DE ARGENTINA S.A.C.I., \$-428, 471, BUENOS
AIRES, ARGENTINA.
ETHNOR PTY. LIMITED, 1-5 KHARTOUM ROAD, NORTH RYDE, N.S.W.
2113, AUSTRALIA
ORTHO PHARMACEUTICA N.V., STATIONSTRAAT 82, TURNHOUT, BELGIUM,
ATTN: MR. VANSWEEVELT
THOMAS MEADOWS AND LTD., SAVENTEM BRUSSELS BELGIUM, TURNHOUT,
BELGIUM FOR ORTHO PHARMACEUTICA NV, STATIONSTRAAT 82.
JOHNSON AND JOHNSON, INDUSTRIA E. COMERCIO, AV. DO ESTADO
5459, SAO PAULO, BRAZIL, 'CX. INTERNA 1753'.
MR. L. MAO, U. S. SUMMIT CORPORATION, ROOM 902, CHIA HSIN
BLDG. 9TH FL, TAIPEI, TAIWAN.
CENTRAL DISTRIBUIDORA INDUSTRIAL S.A., "CEDISA", APARTADO
10.256, SAN JOSE, COSTA RICA.
DISTRIBUIDORA RICHARD O. CUSTER S.A., P. O. BOX 1152,
GUAYAQUIL, ECUADOR.
FARMACIA SAN GABRIEL, PLAZA 14 DE JULIO, SAN SALVADOR, EL SALVADOR
C.A.
CILAG CHEMIE GMBH, MEUE BERGSTRASSE 9, 6146 ALSBACH, GERMANY,
ATTN: KLAUS DATHAN.
CHRISTOPHER PALLIDIS, 15 ALEXANDER SCUTSOU STREET, ATHENS,
T-134, GREECE.
LOXLEY LOBO MEDICAL LTD., G.P.O. BOX 84, KOWLOON, HONG KONG.
KOTHARI SCIENTIFIC AND RESEARCH INSTITUTE, 8 INDIA EXCHANGE
PLACE, RUBY HOUSE, CALCUTTA 700001, INDIA.
THE FINANCIAL ADVISER AND CHIEF ACCOUNTS OFFICER, SOUTHERN
RAILWAY OF MADRAS 23, INDIA.
P. T. TIGARAKSA, JALAN LETGEN S. PARMAN 73, SLIPI, JAKARTA,
INDONESIA.
CILAG CHEMIE ITALIANA SP., VIA COSENZA 5, 20137 MILANO,
ITALY, C/O TACCHI AEROPORTO DI MILANO, ITALY, TELE. #868066.
UNIVERSITY OF WEST INDIES, PATHOLOGY DEPARTMENT, ATTN: HUGH
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PALLISER, KINGSTON 7, JAMAICA W.I.
SANKO JUNYAKU CO. LTD. 10-6 IWAMOT O-CHO, 1 CHOME CHIYODA-
KUTMM BLDG., TOKYO 101, JAPAN.
MINISTRY OF PUBLIC HEALTH, P.O. BOX 5, KUWAIT, ARABIAN GULF.
BIOPHARM, P. O. BOX 8324, BEIRUT, LEBANON.
JOHNSON AND JOHNSON SDN BF, JALAN TANDANG, P.O. BOX 17,
PETALINE JAYA, SELANGOR, MALAYSIA.
JOHNSON AND JOHNSON DE MEXICO SA DE CV, CALZADA ERMITA IXTAPALA,
MEXICO 13, D.F., MEXICO.
JOHNSON AND JOHNSON N.Z. LTD., P.O. ?9/ 2179, ELLERLIE,
AUCKLAND, N.Z.
NATIONAL AND GRINDLAYS BR, P.O. ?9/ 4662, KARACHI, ACCT.
THE EASTERN TRADERS, M. A. JINNAH ROAD, KARACHI, PAKISTAN.
CIA. INTERNATIONAL DE VENTAS S.A., APARTADO 1130, PANAMA 1,
REPUBLICA DE PANAMA.

HOSPITAL MILITAR CENTRAL, LIMA, PERU.
RICHARD O. CUSTER S.A. CASTILLA 681, LIMA, PERU.
PROCUREMENT OFFICER, TRUST TERRITORY OF THE PACIFIC ISLANDS,
SAIPAN, MARIANA ISLANDS, 96950.
ETHNOR LABORATORIES PTY. LTD., P.O. BOX 273, HALFWAY HOUSE
1685, TRANSVAAL, SOUTH AFRICA.
INDO ATLANTIC AIR FREIGHT LTD., SAN SMUTS FOR ETHNOR PTY.
LTD., NEW ROAD, HALFWAY HOUSE TRANSVAAL S. AFRICA
JOHNSON AND JOHNSON S.A., GUSTAVO FERNANDEZ BALBUENA 2,
MADRID 2 SPAIN.
ORTHO DIAGNOSTICS, DIV. OF JOHN AND JOHNSON AB, S-191 84
SOLLENTUNA, SWEDEN, ATTN: MISS WESTIN.
NEW FRENCH DISPENSARY, 693 699 SIPHYA ROAD, BANGKOK, THAILAND.
BOOKER EXPORT SERVICES LIMITED, YORK HOUSE, BLEMONT ROAD,
UXBRIDGE, MIDDX. UB 8 LTD., ENGLAND, UNITED KINGDOM.
ORTHO PHARMACEUTICAL LTD. SAUNDERTON HIGH WYCOMBE, ENGLAND.
ETHNOR FARMACEUTICA S.A., APARTADO 60.349, CHACAO 106, CARACAS,
VENEZUELA, ATTN: MR. LUCIEN JABBOUR.
NATIONAL IMPORT AND EXPORT CORP. LTD., P. O. BOX 572,
NOOLA, ZAMBIA.

5. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY ARE FAMILIAR WITH DETAILS OF RECALL AND
MAY WISH TO APPRAISE HOST GOVERNMENT DRUG CONTROL AUTHORI-
TIES OF RECALL SO THAT THEY MAY TAKE SUCH ACTION AS THEY
DEEM APPROPRIATE.
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KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, RECALLS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 09 DEC 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE269495
Document Source: CORE
Document Unique ID: 00
Drafter: FDA/JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D740357-0512
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19741249/aaaabqes.tel
Line Count: 202
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: MorefiRH
Review Comment: n/a
Review Content Flags:
Review Date: 19 SEP 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <19 SEP 2002 by ReddocGW>; APPROVED <05 FEB 2003 by MorefiRH>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF DIAGNOSTIC PRODUCT - FIBRINDEX
TAGS: ETRD, EIND, TBIO, XX, FDA
To: BUENOS AIRES MULTIPLE
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005